	<p><b>ASSENT TO PARTICIPATE IN A RESEARCH STUDY</b></p> <p>(HFH IRB form rev: 06/2004)</p>	<p>DATE:</p> <p>Study ID:</p> <p>NAME:</p>
<p><b>APPROVAL PERIOD</b></p> <p>Oct 2, 2006 – Jun 19, 2007</p> <p>INSTITUTIONAL REVIEW BOARD</p>	<p><b>PROJECT TITLE:</b></p> <p>Detroit Children's Health Study (M)</p>	

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**Other Investigators:**


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**1. WHY IS THIS RESEARCH BEING DONE?**

Your parent or legal guardian answered a questionnaire about your medical history that asked about things that might make it harder for you to breathe. You are now being asked to be in this research study because your parents (or legal guardian) completed the Health Questionnaire about your health and gave permission for you to participate in the study.

This research is being done to learn more about the things that cause some people to have asthma and others not to and what might make asthma worse. These may include things in your home and things in the air and things that you might eat. There will be about 200 children in this study.

This study is sponsored by the U.S. Environmental Protection Agency (EPA). This means that the EPA is paying HFHS for the costs of carrying out this research.


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## 2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

This study will take place at the Henry Ford Health System clinic and will last approximately 2 hours.

During this study we will ask for your :

- **Medical History:** including the medications you take
- **Vital Signs:** We will measure how much oxygen is in your blood, your blood pressure and your height and weight.
- **Blood:** We will take a 50 ml blood sample (about 10 teaspoons). If you have ever had blood drawn this will be no different. It will involve only one good needle stick. We will not try any more than two times if the first prick doesn't give us blood. We will be testing parts of your blood called genes.
- **Urine Collection:** We will ask you to pee in the toilet like you always do. A special tray will be placed inside the toilet to catch the urine. A nurse will empty this into a special test tube.
- **Fingernail/toenail clippings:** You will be asked to clip your fingernails and toe nails and put them in two separate plastic bags. Your parent or guardian can help you.
- **Smell test:** You will scratch and sniff little paper bubbles containing various smells. You will try to identify 10 smells by marking your answer in a booklet.
- **Breathing Test:** This test measures how fast and how much air you can breathe out. You will be asked to put a tube into your mouth. You will inhale as deeply as possible, and then exhale as fast and completely as possible into the tube. This will be just like blowing out all of the candles on a birthday cake. You will do this strong blow 3-8 times. A researcher will show you how to do this test.
- **Exhaled nitric oxide:** When we breathe, we breathe in small amounts of nitric oxide. This test measures how much nitric oxide (invisible parts of the air) might be in your lungs.
- **Video Presentation:** We will ask you to view a 6 minute video presentation on Asthma and the procedures you will have today.

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- **Home Air Sample Monitoring:** You may have been asked to participate in indoor and outdoor home air monitoring. You might have also been asked to bring in a used vacuum cleaner bag. You may keep the duffle bag that the EPA provided to you to carry in the samples.

### 3. WHAT ARE THE RISKS OF THE STUDY?

Sometimes things happen to people in research studies that may make them feel bad. These are called "risks." We think that the risks of this study are that there is a slight chance that you may feel dizzy or light-headed after strong blows into the machines that will test how well your lungs are working. Some children feel light headed after their blood is taken. You will need to stop and rest if you begin to feel this way. There will also be a doctor or nurse available if you experience any risks.

You may have a bruise on your arm where the blood is taken.

Not all of these things may happen to you. None of them may happen. Or things may happen that the researchers don't know about yet.


### 4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

People may have good things happen to them because they are in research studies. These are called "benefits." There is little chance you will benefit from being in this research study. But you will be helping to better understand why children might get asthma and why some children have different things that trigger or worsen their asthma. You will receive a small gift after having your blood taken. Your parent/guardian will receive blood lead level information if your level is not good. They will receive some other information on your test results. There is no other direct benefit to you other than knowing that you will be helping other children who may get asthma in the future.

### 5. WHAT OTHER OPTIONS ARE THERE?

You have the choice of not participating in this part or any other part of this research study.



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**6. WHAT ABOUT CONFIDENTIALITY?**

No one other than the researchers involved in the study will be told the things we learn about you in this study.

**7. WHAT IF I AM INJURED?**

It is very unlikely that you will be hurt as a result of taking part in this project. There is no federal, state or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. Your parent/guardian and/or any medical insurance may have to pay for any medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent.

**8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?**

Dr. Ganesa R. Wegienka, Epidemiologist, or her staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Dr. Wegienka at (313) 874- 7393.


If you have questions about your child's rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 916-2024. The IRB is a group of people who review the research to protect the rights of research participants.

**9. DO I HAVE TO PARTICIPATE IN THIS STUDY?**

Your parent/guardian has given permission for you to be in this study. You do not have to be in this study if you don't want to. You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you.

**10. WHO ELSE CAN STOP MY PARTICIPATION?**

The people in charge of the project or your parents can also end your participation in the project.

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**11. WILL IT COST ANYTHING TO PARTICIPATE?**

It will not cost anything to be in this study. We do not expect there to be any additional costs to your parent/legal guardian if you participate in this study.

**12. WILL I BE PAID TO PARTICIPATE?**

You will not directly be paid any money for being in our research study. You will get a small gift if you attempt to give blood. Your parent/legal guardian will be paid for your participation in the study. The amount will depend on whether we are able to collect some or all the samples and conduct the breathing tests. Transportation costs may be covered as well.

**13. ASSENT**

You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any words you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

_____ Signature of child	_____ Date	_____ Time
_____ Print name of child		
_____ Witness to Signature	_____ Date	_____ Time
_____ Signature of Person Obtaining Consent	_____ Date	_____ Time